

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0495]

DMS

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**Prescription Drug User Fee Act (PDUFA) II Five-Year Plan—FY 2001 Update;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled "PDUFA II Five-Year Plan—FY 2001 Update." The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in fiscal year (FY) 1998, FY 1999, and FY 2000 and updated projections for FY 2001 and FY 2002.

DATES: Submit written comments on the plan at any time. Comments will be considered as the agency makes annual adjustments to the plan in the second quarter of each FY.

ADDRESSES: Submit written requests for single copies of this plan to the Office of Management and Systems (HF-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Attn: Frank Claunts. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the plan to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the plan.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management Systems (HF-300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an internal planning document entitled "PDUFA II Five-Year Plan—FY 2001 Update." The Prescription Drug User Fee Act of 1992 (PDUFA) was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997. The amended and extended PDUFA is referred to as PDUFA II. PDUFA II authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 1997 and to achieve the even more stringent new goals.

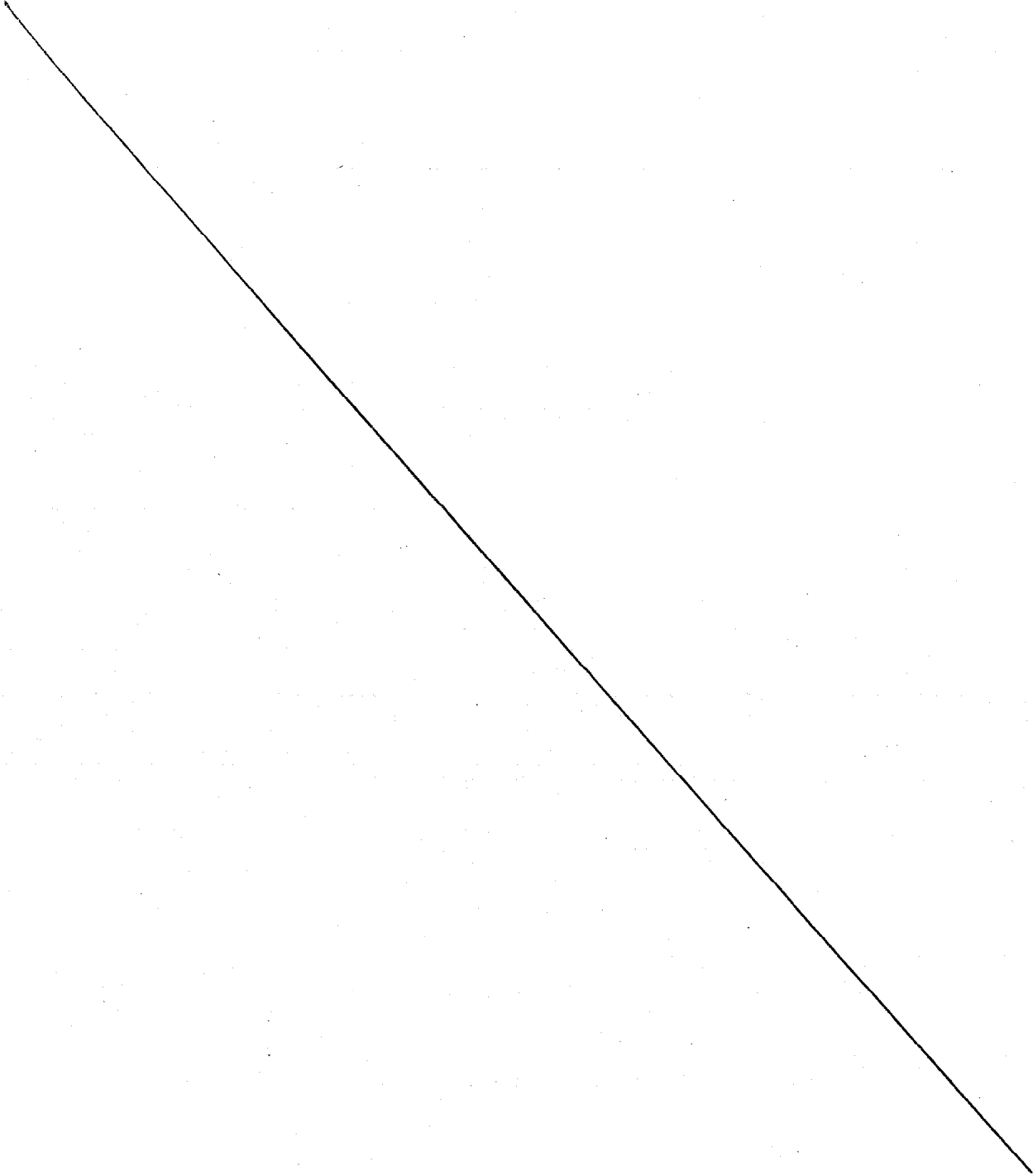
The updated FY 2001 plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and updates the 10 major assumptions on which the plan is based. This is the third update of the plan since it was initially published in July 1998. The updated plan summarizes individual plans of agency components with major PDUFA responsibilities and also provides a consolidated agency summary. The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in FY 1998, FY 1999, and FY 2000 and updates projections for FY 2001 and FY 2002. Attachments include the **Federal Register** notice of December 18, 2000 (65 FR 79107), establishing prescription drug user fee rates for FY 2001, updated 5-year estimates of PDUFA fees and revenues, and the revised PDUFA II Information Management Five-Year Plan.

We are making this plan available to all that have an interest. We welcome comments and will consider them in the future as annual adjustments are made to the plan.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the plan at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The FY 2001 update and received comments

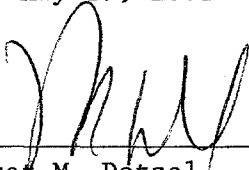
are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

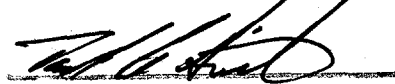
Persons with access to the Internet may obtain the document at <http://www.fda.gov/oc/pdufa2/5yrplan.html>.

Dated: 5-17-01
May 17, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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